UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,434	06/13/2006	Olivier Gerard	2003P03001WOUS	6582

28159 7590 08/15/2011

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P.O. BOX 3001
Briarcliff Manor, NY 10510-8001

EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
08/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

debbie.henn@philips.com
vera.kublanov@philips.com
marianne.fox@philips.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,434	GERARD ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. ***Claims 1 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Hiam et al. (US 6,574,492 B1) in view of Chia et al. (6,233,477 B1) in view Asahina et al. (US 5,357,550).***

Regarding Claim 1, *Ben-Haim et al.* (hereinafter *Ben-Haim*) suggests a medical system comprising:

a medical instrument *(catheter #1)* to be guided in a patient body *(col. 3, ll. 3 – 5)*; and an

X-Ray acquisition means capable of acquiring a two-dimensional X-ray image of said medical instrument *(col. 33, ll. 53 – 59).*

Ben-Haim also suggests a second catheter *(catheter #2)* that is capable of acquiring a three-dimensional location/positional data set of said medical instrument *(col. 13, ll. 4 – 6; and col. 23, ll. 28 – 40).*

Ben-Haim also suggests that the catheter #2 may be localized or imaged by the X-ray acquisition means *(col. 23, ll. 53 - 59);* Ben-Haim is capable of providing localization of catheter #2 within a referential of said X-ray acquisition means.

Ben-Haim differs from Claim 1 in that Ben-Haim does not suggest that *catheter #2 c*omprises an ultrasound acquisition means using an ultrasound probe (or transducer) to acquiring a three-dimensional location/positional (ultrasound) data set of said medical instrument,

Nonetheless, Chia et al. *(hereinafter Chia)* provides a dual-catheter system wherein one of the catheter tracks the position of the second catheter with the use of an ultrasound imaging transducer located on the first catheter *(col. 2, line 39 – col. 3, line 3; col. 3, line 58 – col. 4, line 3; and col. 4, ll. 32 – 33 and 41 – 42).*

Additionally, Asahina et al. *(hereinafter Asahina)*suggests that it is possible to provide a localization of said ultrasound probe within a referential of said X-ray acquisition means *(Abstract; col. 2, ll. 49 – 53; and col. 5, ll. 37 – 40).*

Furthermore, Ben-Haim in view of Chia is capable of selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means.

Furthermore, Ben-Hiam in view of Chia in view of Asahina is capable of converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe, and capable of generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization, as this only requires processor capabilites, which are disclosed by Asahina *("image processor," **(14)**)*, by Ben-Hiam *("computer," (51))*, and by Chia *("data acquisition computer," **(38)**).*

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Hiam and Chia before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system teachings of Ben-Haim with dual-catheter-

positioning-system using ultrasound imaging teachings of Chia so that one could obtain optimal 3D localizing of the medical instrument *(Chia: col. 4, line 9)*.

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Hiam in view of Chia and Asahina before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system using ultrasound imaging teachings of Ben-Haim in view Chia of with the x-ray "radiographing" of an ultrasonic probe of Asahina so that one could obtain additional information about the medical instrument by using a dual-imaging system *(Asahina:col.5, ll. 31 – 55)*.

Regarding claims 2 – 5 and 9 – 13, Ben-Hiam in view of Chia in view of Asahina is capable of performing claimed functions as they only require the use of a processor, which is disclosed by Ben-Hiam, Chia, and Asahina, as discussed in the rejection of Claim 1 above.

Regarding claims 7 and 8, Ben-Hiam in view of Chia in view of Asahina suggests a system as claimed in claim 1, wherein said ultrasound probe is equipped with at least three non aligned and interdependent radio-opaque markers *("piezoelectric markers") (see aforementioned citations of Chia)* and said localization means are intended to localize said markers in at least a first 2D X-ray image having a first orientation angle in said referential *(Asahina: col. 5, ll. 56 – 61 and col. 6, ll. 21 – 24)*; and wherein said localization means (via processor) are capable of further localize said markers in a second 2D X-ray image having a second orientation angle in said referential.

2. ***Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Hiam in view of Chia in view Asahina) in view of Kockro (US PG Pub 2004/0254454 A1).***

Regarding Claim 14, *Ben-Haim in view of Chia in view of Asahina* suggests a medical system comprising:

acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system, acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, and localizing said ultrasound probe in a referential of said X-ray acquisition system *(see rejection of Claim 1)*.

However, Ben-Haim in view of Chia in view of Asahina differs from Claim 14 in that Ben-Haim in view of Chia in view of Asahina does not suggest specifically selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system.

Nonetheless, Kockro suggests selecting a region of interest (with use of a "bounding box") of a tracked medical instrument within a 3D image data set that define a first localization of said region of interest within a referential of the imaging system (paragraphs [0045 – 0046].

Ben-Haim in view of Chia in view of Asahina suggests converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system by virue of the fact that the ultrasound catheter probe is being tracked by the X-ray acquisition system (see rejection of Claim 1).

Ben-Haim in view of Chia in view of Asahina generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization *(Asahin: col. 5, line 27 – col. 6, line 24)*.

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Hiam in view of Chia in view of Asahina and Kockrobefore one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system using ultrasound imaging with the x-ray "radiographing" of an ultrasonic probe teachings of Ben-Haim in view of Chia in view of Asahina with the bounding box teachings of Kockro so that one could obtain a more realistically" corresponding position of the medical instruemnt with respect to the corresponding imaging system *(Kockro: paragraph [0046]).*

Response to Arguments

3. Applicant's arguments and claim amendments on p. 5, paragraph 1, filed June 1, 2010, with respect to claims 1 – 13 have been fully considered and are persuasive. The 35 U.S.C. §112, second paragraph, rejections of these claims have been withdrawn.

4. Applicant's arguments filed June 1, 2010 have been fully considered but they are not persuasive.

In response to Applicant's arguments on p. 6, paragraphs 2 and 3, Examiner respectfully points out that the claims require that an x-ray acquisition device be provided for the present apparatus. Ben-Haim provides that. Claims 1 – 13 do not include method steps for obtaining an x-ray image; therefore, *how* Ben-Haim et al. obtains an x-ray image is irrelevant. Even method claim 14 does not pertain to actual steps of obtaining an x-ray image; just that a step of obtaining an x-ray image be performed. Ben-Haim et al. clearly provides a step of obtaining an x-ray image. Examiner also points out that the claims do not recite the need for a *bi-modal* x-ray imaging device; only that the display component should be *capable* of displaying a bi-modal x-ray image. Any display is capable of displaying a bi-modal x-ray image. Applicant is also

reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If Applicant feels that a providing a bi-modal x-ray apparatus is a pertinent feature pertaining to the patentability of the present application, then it must be recited in the claims. This response applies also to Applicant's arguments with respect to Chia et al. on p. 6, paragraph 3.

Furthermore, in response to applicant's arguments against the references individually (that is, whether Chia et al. or Aashina et al. provide bi-modal x-ray imaging; or whether Chia et al. provides any kind of imaging; or whether Aashina et al. provides 3D ultrasound), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that Aashina et al. shows time-matched ultrasound and fluoroscopy images on separate displays so that concurrently acquired fluoroscopy images can be received and shown at the same time, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In any case, Examiner asserts that this ability cited by Applicant along with teaching in col. 2, ll. 49 - 53 suggests that it is possible to provide localization of said ultrasound probe with a referential of said x-ray acq. Means (see rejection of claim 1 for more details).

In response to Applicant's arguments on p. 8, second paragraph, that in Kockro, the bounding box "only delineates the surgical site, in this patent, surrounding the head; [and that a] surgical instrument could be anywhere in the head and is thus not spatially defined by the box," Examiner respectfully points out that the surgical site comprises the medical/surgical instrument, and as the bounding box defines the entire surgical site (as Applicant himself contends), the bounding box provides localization of the "region of interest around the medical instrument," as required by the claim.

Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777